

### REMARKS

After entry of this Amendment, claims 1-10 and 63-67 are pending in the application. In an earlier response, claims 11-31, 42-53, 56-58, 61 and 62 were cancelled, and claims 32-41, 54, 55, 59 and 60 were withdrawn from consideration. Claims 1-10 and 63-67 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Ayres. With this Response, Applicant has amended claims 1, 3 and 63.

#### **Rejection under 35 U.S.C. § 102(b)**

Claims 1-10 and 63-67 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Ayres. Applicant's amended independent claims 1, 3 and 63 each require a lancet holder arranged and configured to hold the second end of the lancet and move the lancet to penetrate the skin of a patient with the first and second sharpened tips. The amendments simply clarify the relationship between the lancet and the lancet holder.

Ayres teaches a needle for use with a Vacutainer designed so that the needle is not deflected when entering a stopper or does not core the stopper. (Abstract, Col. 1, lines 36-50). Initially, the needle for penetrating a stopper was provided with a pair of opposed bevel-faces, shown in Figs. 1 and 3. This needle, however, would cut a core out of the rubber stopper. (Col. 2, lines 19-29). To avoid this, Ayres teaches bending the beveled faces inward in abutting relationship, as shown in Figs. 2, 4 and 8. (Col. 2, lines 30-35).

The Examiner contends that the Vacutainer tube is held and moved by a healthcare provider or a user to penetrate a patient's skin to withdraw a blood sample and it is therefore equivalent to Applicant's recited lancet holder. However, the Examiner does not indicate where Ayres discusses the end of the needle that penetrates the patient because Ayres does not address that end of the needle at all. Ayres only discusses the end of the needle that enters the stopper of the Vacutainer. The Background of the Invention states that **the needle point penetrates the rubber stopper**. The needle occasionally embeds in the sidewall of the stopper instead of the well of the tube, "**whereupon no blood can enter the Vacutainer tube and the device is a failure.**" (Col. 1, lines 9-14). Figure 5 clearly shows the needle tips inside the

Vacutainer. A principal object of the invention is to produce a needle that does not deflect during stopper penetration. (Col. 2, lines 36-40). "A further object is to provide a needle point for stopper penetration . . ." (Col. 2, lines 42-43). The claims all recite a "stopper penetrating needle." (Col. 3, lines 4 – 16). There is no teaching in Ayres of using that end of the needle to penetrate the skin of a patient.

Applicant submits that the Ayres reference fails to teach a lancet device with a lancet holder arranged and configured to hold the lancet by the second end and move the lancet to penetrate the skin of a patient with the end with the sharpened tips. Because the Ayres reference does not teach or suggest all of the limitations of independent claims 1, 3, and 63, these claims are not anticipated by Ayres. Applicant respectfully submits that the Examiner's rejection is overcome and that claims 1, 3, and 63 are in condition for allowance.

Claims 2, 4-10 and 64-67 depend from one of independent claims 1, 3 and 63 to contain all of the limitations therein. Because of this dependency, Applicant respectfully submits that the Ayres reference does not teach or suggest all of the limitations of dependent claims 2, 4-10 and 64-67, these claims are not anticipated by Ayres. Applicant respectfully submits that claims 2, 4-10 and 64-67 are in condition for allowance.

## **Conclusion**

It is respectfully submitted that this Response traverses and overcomes all of the Examiner's objections and rejections to the application as originally filed. It is further submitted that this Response has antecedent basis in the application as originally filed, including the specification, claims and drawings, and that this Response does not add any new subject matter to the application. Reconsideration of the application is requested.

If the Examiner feels that prosecution of the present application can be expedited by way of an Examiner's amendment, the Examiner is invited to contact the Applicant's attorney at the telephone number listed below.

Respectfully submitted,



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